K041840

AUG 2 0 2004

510(k) SUMMARY

Submitted by:	MEDX, Incorporated 3456 N. Ridge Ave. #100 Arlington Height, IL 60004
Telephone:	(847)-463-2020
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Contact Person:	Floyd R. Rowan, Executive Vice President
Date Summary Prepared:	July 6, 2004
Trade Name of Device:	MEDX NuQuest™ - InteCam™ SPECT 37-75 System.
Common Name	Gamma Camera System.
Classification:	This device is classified as a Class II Device. Radiology Panel. Classification Name: System, Tomography, Computed, Emission. Ref. 21CFR892.1200, Product Code: KPS.
Substantial Equivalence:	The MEDX NuQuest – InteCam SPECT 37-75 is substantially equivalent to the Siemens Integrated ORBITER™ Gamma Camera System.

Intended Use:

The intended uses of the MEDX NuQuest™- InteCam™ SPECT 37-75 System are the acquisition, processing, display and analysis of planar and SPECT nuclear images of all organ systems using approved pharmaceuticals.

Description of Device:

The MEDX NuQuquest™ - InteCam™ SPECT 37-75 System is a Nuclear Medicine Gamma Camera System consisting of:

- A modified (remanufactured) Siemens Digitrac™ Orbiter™ Gamma Camera and its associated Gantry which also was modified to operate with our computer (see bullet below) and software.
- NuQuest™ Nuclear Medicine Computer and related software.

The modification to the Siemens Orbiter Gamma Camera consisted of removal of certain low voltage circuit boards in the gamma camera and the gantry portions of the Siemens" device and installing proprietary low voltage circuit boards that allow the use of our NuQuest™Nuclear Medicine Computer to replace the Siemens computer and related imaging software.

The Detector (Gamma Camera) portion of the system may have 37 or 75 photomultiplier tubes depending on whether the Siemens Digitrac 3700 or 7500 were converted to operate with the MEDX NuQuest Computer and its software.

It should be pointed out that the NuQuest Nuclear Medicine Computer has a cleared 510(k): K953255.The imaging software (under the trade name IM512P) also has a cleared 510(k): K945792.

Note: Digitrac and Orbiter are registered trademarks of Siemens Gammasonic, Inc.

Scientific Principle:

Diagnostic Nuclear Medicine began in early 1950's with the availability of short half-life isotopes. Isotopes such as I131 were injected into the patient and were selectively taken up by organ systems such as the thyroid. Measurement of the resulting radioactivity in the organ provided information on both the size of the organ and the relative amount of the isotope taken up.

Nuclear Medicine cameras work on the principle similar to television cameras. A collimator (lens) "focuses" gamma rays on a scintillation crystal. The scintillation crystal converts gamma rays into light. Photomultiplier tubes are then used to convert the light into electrical signal proportional to the energy of the detected gamma ray.

Early instruments used a single hole lead collimator and detector that was moved in a raster pattern forming a 2-D image of the organ of interest. In the late 1950's

methods were developed for directly obtaining a 2-D image by using a large crystal with multiple photomultiplier tubes and electronically calculating the position and energy of the gamma event. Two dimensional projections collected at many positions can be mathematically combined to yield a three dimensional representation of the data. This principle of tomographic reconstruction was discovered early in this century, but it was not until the advent of high speed computer that the technique could be successfully applied in diagnostic imaging first to CT then to Nuclear Medicine and MRI.

Nuclear Medicine is currently of great interest because of its high contrast, and relatively low cost per study. The ability to attach isotopes to substances that are selectively taken up by specific tissue types can provide very high contrast by the organ of interest and the surrounding tissue. This has tended to compensate for the relatively poor spatial resolution of Nuclear Medicine compared to other modalities such as MRI.

In addition the uptake and clearing of the radioisotopes can be observed temporally, providing an indication of the biological activity of the tissue. This is important when attempting to determine tissue viability, or finding areas of abnormal activity such as cancerous tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

Mr. Floyd R. Rowan
Executive Vice President
MEDX, Inc.
3456 N. Ridge Ave., #100
ARLINGTON HTS IL 60004

Re: K041840
Trade/Device Name: MEDX NuQuest™ – InteCam™ SPECT 37-75 System
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: July 7, 2004
Received: July 8, 2004

Dear Mr. Rowan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041840

Device Name: MEDX NuQuest™- InteCam™ SPECT 37-75 System

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041840